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rotation MEDICAL

510(k) Summary

Applicant Information

Applicant Name:	Rotation Medical, Inc.
Applicant Address:	15350 25th Avenue North, Suite 100 Plymouth, MN 55447
Telephone:	763-746-7502
Fax:	763-746-7501
Contact Person:	Jeff Sims Vice President, Clinical Programs and Regulatory Affairs
Date Prepared/Revised:	August 22, 2011/November 14, 2011/December 13, 2011

Name of Device

Device Common Name:	Tendon Protector
Device Trade Name:	Collagen Tendon Sheet
Device Classification Name:	Mesh, Surgical 878.3300 Class II FTM

Legally Marketed Devices to Which Substantial Equivalence is Claimed

Predicate Device(s):	Collagen Tendon Wrap, K0080452 Collagen Matrix, Inc., Oakland, NJ

Description of the Device

Collagen Tendon Sheet is a resorbable type I collagen matrix that provides a layer of collagen over injured tendons. Collagen Tendon Sheet is designed to provide a layer between the tendon and the surrounding tissue. When hydrated, Collagen Tendon Sheet is an easy-to-use, soft, pliable, nonfriable, porous collagen sheet. Collagen Tendon Sheet is provided sterile, non-pyrogenic, for single use only, in a variety of sizes, in double peel packages.

Intended Use

Collagen Tendon Sheet is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

Summary/Comparison of Technical Characteristics

Collagen Tendon Sheet and its predicate device have the same technological characteristics. In particular, Collagen Tendon Sheet and its predicate are the same with respect to intended use, design, materials, and material characterization. The substantial equivalence of the Collagen Tendon Sheet and its predicate was demonstrated primarily based on in vitro characterization studies, biocompatibility studies, an animal efficacy study, and clinical experience of the predicate device. In vitro characterization studies included evaluation of material properties, biological properties, chemical and physical properties.

The Collagen Tendon Sheet and its predicate device are manufactured with similar processing, in the same facilities, by the same manufacturer, using the same raw materials. They vary with respect to size and thickness. In addition, the Collagen Tendon sheet is provided in a flat form.

Collagen Tendon Sheet and its predicate have been characterized for chemical composition, purity, density, and strength to demonstrate substantial equivalence. Testing was conducted in accordance to FDA's Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh.

Collagen Tendon Sheets have been evaluated in a number of in vitro and in vivo tests to assess its safety/biocompatibility. The device passed all applicable FDA Blue Book Memorandum G95-1and ISO 10993-1 testing for the biological evaluation of medical devices.

An animal efficacy study was conducted to evaluate the device as compared to its predicate device. No clinical tests were performed on the product; however clinical history of the predicate device was referenced in the submission.

Viral inactivation studies were performed to ensure the viral safety of the product.

Conclusion of Non-clinical Studies

The results of the *in vitro* product characterization studies, *in vitro* and *in vivo* biocompatibility studies, as well as the animal efficacy study show that Collagen Tendon Sheet is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Rotation Medical, Incorporated
% Mr. Jeff Sims
Vice President, Clinical Programs and Regulatory Affairs
15350 25th Avenue North, Suite 100
Plymouth, Minnesota 55447

Re: K112423
Trade/Device Name: Collagen Tendon Sheet
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: December 16, 2011
Received: December 16, 2011

Dear Mr. Sim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

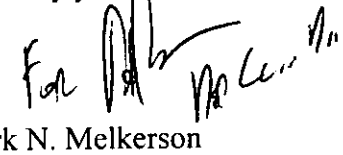
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112423

Confidential
Rotation Medical, Inc.

Indications for Use

510(k) Number (if known): _____

Device Name: Collagen Tendon Sheet

Indications for Use:

Collagen Tendon Sheet is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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